

REMARKS

Claim 6 was rejected under 35 USC 112, second paragraph as being redundant. Claim 6 has been cancelled.

The Examiner indicates that Figures 8a-8C were not included with the filing of the present application. Applicant has included a full set of drawings, including those indicated as missing and respectfully requests that they be added to the file. No new matter has been added. Applicant also notes that Provisional application 60/191,075, was filed on March 21, 2000 and the present application claims the benefit of that provisional filing. By the present amendment, the Provisional application has been formally incorporated by reference and forms an alternative basis to introduce the Figures, which were submitted with the provisional filing.

Claims 1, 3, 4 and 6-9 were rejected under 35 USC 102(b) as being anticipated by Gunderson. Claims 5, 10 and 11 were rejected under 35 USC 103(a) as being unpatentable over Gunderson in view of Rossing. These rejections are respectfully traversed.

By the above amendments, claim 3 has been cancelled and its elements added to independent claim 1. Claims 4 and 5 have been rewritten in independent form and include all of the elements of former claim 1. Applicant respectfully asserts that the amended claims are allowable over the references of record.

Gunderson teaches a method and apparatus for discriminating between tachycardia and fibrillation that measures the intervals separating depolarizations, sorts the intervals into ranges and based on the distribution of ranges, identifies tachycardia or fibrillation. The reference fails to teach "means for defining a discrimination criterion based on determining whether designated ones of the plurality of interval range bins have at least a predetermined threshold number of measured depolarization intervals within them." Specifically, the reference fails to teach an apparatus wherein "the threshold number is set as

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a value which increases as an inverse function of the length of the intervals between depolarizations,” as specified in claim 1.

Likewise, the reference fails to teach an apparatus “wherein the threshold number is set as a value which increases as an inverse function of a defined percentile of the length of intervals over a sequence of a predetermined number of intervals between depolarizations,” as specified in claim 4. Nor does the reference teach an apparatus wherein the “threshold number is set as a value which increases as an inverse function of the 75th percentile of the length of intervals over a sequence of a predetermined number of intervals between depolarizations,” as specified in claim 5. These particular threshold determinations serve to further increase the accuracy of the arrhythmia determination. As such, Gunderson fails to anticipate these claims.

With respect to amended claims 1 and 4, the Examiner asserts that these elements are shown in Gunderson at Col 2, line 63 to Col 3, line 25. A careful reading of these sections clearly indicates that such teachings are absent. That is, Gunderson does teach sorting events into bins and making a determination as to the particular arrhythmia; however, there is no teaching as to setting the threshold number based on inverse functioning criteria presently claimed.

With respect to claim 5, the Office Action indicates that Gunderson fails to teach “the threshold value increasing as a function of the 75th percentile of the length of the intervals of a predetermined number of intervals.” The Examiner then asserts that Rossing provides such a teaching.

As previously discussed, Rossing discloses a technique wherein a programmable fibrillation detection interval range and a programmable tachycardia detection interval range are adjacent to one another. In particular, the interval range designated as indicative of fibrillation consists of intervals less than a programmable interval (FDI) and the interval range designated as indicative of ventricular tachycardia consists of intervals less than a programmable interval (TDI) and greater than or equal to FDI. Measured R-R intervals, out of a preceding series of a predetermined number (FEB) of intervals,

falling within each of these two ranges are separately counted. That is, a count (VTEC) of R-R intervals falling within the tachycardia interval range, and a count (VFEC) of the number of intervals falling within the fibrillation interval range are made. VTEC is incremented in response to R-R intervals that are greater than or equal to FDI but shorter than TDI, and is reset to zero in response to intervals greater than or equal to TDI and is insensitive to intervals less than FDI. VTEC is compared to a programmed value (VTNID) and VFEC is compared to a corresponding programmable value (VFNID). When one of the counts equals its corresponding programmable value, the criterion for the presence of the corresponding arrhythmia, i.e. fibrillation or tachycardia, is met. An appropriate therapy, e.g. anti-tachycardia pacing, a cardioversion pulse or a defibrillation pulse, is then delivered. Whereas Rossing discriminates on the basis of determining which of two interval ranges has the most counts, the present invention examines the relative distribution of the measured depolarization intervals.

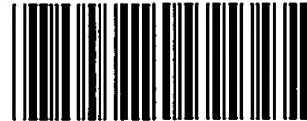
The Examiner appears to have focused on the binary criteria disclosed by Rossing that indicates when one of the other of the intervals has been satisfied. That is, if, for example, 50% or 75% of the recorded events fall within a given interval, then the appropriate counter is incremented (Col. 4, lines 4-17). This does not teach an apparatus wherein the "threshold number is set as a value which increases as an inverse function of the 75th percentile of the length of intervals over a sequence of a predetermined number of intervals between depolarizations," as specified in claim 5. As such, this reference fails to remedy the deficiencies noted in Gunderson.

In consideration of the amendments to the claims and the remarks presented herein, Applicant submits that all pending claims are now in condition for allowance and requests that a notice of allowance issue in due course.

Respectfully submitted,

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Date


Atty: Daniel G. Chapik
Reg. No. 43,424
(763) 514-3066



27581

A New VT/VF Discriminator for Implant

Robert W. Stadler, PhD, Bruce D. Gunderson, MS, Jeffrey A. Medtronic Inc., Minneapolis

DATABASES

Algorithm Development Database: 107 VTs and 203 VTs (53% total) and 5% Spontaneous from 95 patients. Spontaneous episodes were excluded from the CEEM DR™ clinical study. Spontaneous episodes that received therapy before the 18th cycle of the arrhythmia were excluded.

Performance Evaluation Database: 244 VTs and 323 VTs (54% total) and 4% Spontaneous from 161 patients. The patients that contributed to the Algorithm Development Database did not contribute to the Performance Evaluation Database. Spontaneous episodes were excluded from the CEEM DR™ clinical study. Spontaneous episodes that received therapy before the 18th cycle of the arrhythmia were excluded.

Classification of the Gold Standard Classification: Classification of VT or VF was made by a panel of experts from Medtronic. Lead ECG and surface ECG data were available. Arrhythmias were classified as VT and ventricular fibrillation was identified as VF.

RESULTS

Figures 2 and 3 are examples of arrhythmias in the Performance Database for short interval thresholds of 120 ms and 240 ms. Very few VTs or VTs were misclassified by the algorithm. Classification of VTs improved when the short interval threshold was increased from 120 ms to a more realistic value (Figure 3).

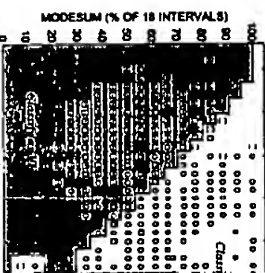


Figure 2: A scatter plot showing the performance of the New Discriminator for the case of short interval threshold of 120 ms.

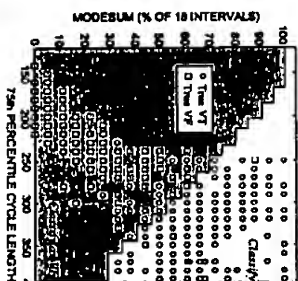


Figure 3: Performance of New Discriminator on the Performance Database when the short interval threshold was 240 ms.

THE NEW VT/VF DISCRIMINATOR

For arrhythmias that achieve VF detection criteria:

- Compare the Modexsum from a histogram of the last 18 cycle lengths before VF detection. Intervals shorter than a programmable short interval threshold are excluded from the Modexsum calculation (but the discriminator remains 18).
- Compare the 75th percentile of cycle lengths for the arrhythmia (i.e., the 4th longest interval out of the last 12).
- Classify the arrhythmia as VT if the Modexsum exceeds a threshold which decreases linearly as the 75th percentile of cycle lengths increases.

Figure 1 is an example of the Modexsum and the 75th percentile of cycle lengths from a histogram of the last 18 cycle lengths before VF detection. The design of the New VT/VF Discriminator is also displayed in Figure 1. The short interval threshold for this figure is the modexsum value of 120ms.

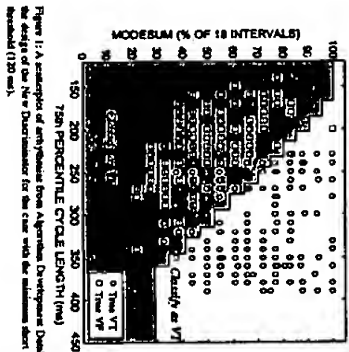


Figure 1: A scatter plot showing the performance of the New Discriminator for the case of short interval threshold of 120 ms.

Abstract A new VT/VF Discriminator for Implantable Cardioverter Defibrillator (ICD) is described. The new VT/VF Discriminator is designed to provide a more accurate and reliable classification of VT and VF than the current ICDs. The new VT/VF Discriminator is designed to provide a more accurate and reliable classification of VT and VF than the current ICDs. The new VT/VF Discriminator is designed to provide a more accurate and reliable classification of VT and VF than the current ICDs.

Keywords: VT/VF Discriminator, Implantable Cardioverter Defibrillator, VT, VF, Modexsum, 75th Percentile, Short Interval Threshold.

Introduction: The new VT/VF Discriminator is designed to provide a more accurate and reliable classification of VT and VF than the current ICDs. The new VT/VF Discriminator is designed to provide a more accurate and reliable classification of VT and VF than the current ICDs.

Results: The new VT/VF Discriminator is designed to provide a more accurate and reliable classification of VT and VF than the current ICDs. The new VT/VF Discriminator is designed to provide a more accurate and reliable classification of VT and VF than the current ICDs.

Conclusion: The new VT/VF Discriminator is designed to provide a more accurate and reliable classification of VT and VF than the current ICDs. The new VT/VF Discriminator is designed to provide a more accurate and reliable classification of VT and VF than the current ICDs.

INTRODUCTION

- The majority of VTs can be terminated successfully by anti-tachycardia pacing (ATP), yet VTs are often detected as VF and treated inappropriately with shocks.
- Mean or median cycle lengths are a poor discriminator of VT from VF.
- Advanced discrimination of VT from VF are necessary to decrease the delivery of shocks for arrhythmias that can be terminated by ATP.

EXISTING VT/VF DISCRIMINATORS

All of the discriminators have a "short interval threshold." Cycle lengths that are shorter than the short interval threshold lead to classification of VF. Selection of the short interval threshold is a tradeoff between VT sensitivity and VF sensitivity.

- Simple Rate Discriminator: If 75% of the cycle lengths are shorter than a programmable short interval threshold (the VF threshold), classify the rhythm as VF.
- Medtronic Fast VT™ VF algorithm:
 - If the arrhythmia achieves VF rate criteria but the last 18 cycle lengths before VF detection are longer than a programmable short interval threshold, the episode is classified as a Fast VT rather than VF.
- Medtronic Javel AICD™ VT/VF Discriminator:
 - Compare the "Modexsum" from a histogram of the last 18 cycle lengths before standard VF detection. The Modexsum, a measurement of regularity, is the sum of the two largest bins in the cycle length histogram.



- Intervals shorter than a fixed short interval threshold of 240 ms are excluded from the Modexsum calculation (but the discriminator remains 18).
- If the Modexsum is > 120/18 (72%), classify as Fast VT rather than VF.